UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,767	12/13/2003	Karin Jarverud	P03,0500	1791

7590 07/05/2006

SCHIFF HARDIN & WAITE
Patent Department
6600 Sears Tower
233 South Wacker Drive
Chicago, IL 60606

EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,767	JARVERUD ET AL.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-43* is/are rejected.

7)☒ Claim(s) *34 and 43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040423*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/18/2006.

2. Applicant's election without traverse of claims 23-43 in the reply filed on 4/18/2006 is acknowledged.

Claim Objections

3. Claims 34 and 43 are objected to because of the following informalities: "sensing or an R-wave" should read "sensing of a R-wave". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 23-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the first/second pacing electrode and first/second sensing electrode are separate elements or the same element. Because the specification indicates that the electrodes may be the same electrode, Examiner has interpreted them to be either the same or separate.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 23, 25, 26, 31, 32, 35, 40, and 41 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Florio et al. (US 2001/0049542, hereinafter "Florio").

10. In regards to claim 23, Florio discloses a method comprising implanting a housing into a subject suffering from CHF (par. 0023) comprising a first pacing and sensing circuit and electrode for a first ventricle, and a second pacing and sensing circuit and electrode in a second ventricle (Fig. 2). Further, the control circuit detects an evoked response during a first time interval and an R-wave from another ventricle at a second interval during a first time window (par. 0112 "if a negative peak is detected...is interpreted as an evoked response", and par. 0114 "a second event detection at some time interval after the first event") and operates the pacing and control circuits accordingly. Lastly, Florio inherently discloses determining that pacing pulses have been delivered substantially simultaneously (par. 0077) because the pulses are delivered through a bifurcated connector (i.e. necessarily "substantially simultaneously"). Alternatively, it is well known in the art of resynchronization therapy to determine whether pacing pulses have been delivered substantially simultaneously to establish whether resynchronization therapy is needed or successful. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Florio's invention with a means to determine whether pacing pulses have been delivered substantially simultaneously to establish whether resynchronization therapy is needed or successful.

11. In regards to claim 25, the same method performed by the first sensing and pacing circuit is performed by the second sensing and pacing circuit because the pulses are delivered and sensed through a bifurcated connector.

12. In regards to claims 26 and 35, the first and second pacing circuits are operated in a first manner if (a/c) is not fulfilled and (b/d) is fulfilled (196) and a second manner if neither are fulfilled (195). The "manner of operation" is the recognition of the two states.

13. In regards to claims 31 and 40, the first interval begins at 0ms after delivery and ends at between 16ms and 40ms (par. 0112).

14. In regards to claims 32 and 41, the first time window inherently begins between 0 and 150ms after the pacing pulse because it begins after the first interval (16-40ms).

15. Claims 33, 34, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio. Florio discloses the essential features of the claimed invention, including a time window of undisclosed length (190), but does not expressly disclose a window ending before 400ms after the pacing pulse or providing a blanking window in the first time window. It is well known in the art to end sensing windows for far-field signals before 400ms to avoid sensing of irrelevant data that extends beyond the physiological V-V delay of 120-150ms and to provide blanking windows to avoid sensing of unwanted signals that occur at consistent, predictable time periods. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Florio's invention by ending sensing windows for far-field signals before 400ms to avoid sensing of irrelevant data that extends beyond the

physiological V-V delay of 120-150ms and to provide blanking windows to avoid sensing of unwanted signals that occur at consistent, predictable time periods.

16. Claims 24, 27-30, and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio in view of Yonce et al. (US 2003/0083711, hereinafter "Yonce"). Florio discloses the essential features of the claimed invention including varying the energy of the pacing pulses if (a/c) is not fulfilled and (b/d) is fulfilled (202) a predetermined number of times (1), and optimizing "pacing parameters" as the occurrence of (a/c) and (b/d) vary (par. 0118). Florio does not explicitly disclose implanting the device in a subject suffering from bundle branch block, detecting fusion if (a/c) and (b/d) are not fulfilled, or modifying a time period based on (a/c) and (b/d) being fulfilled. Yonce teaches of providing a biventricular pacer with capture verification to patients with bundle branch block (par. 0007) to provide ventricular synchronization to patients lacking synchronization and detecting fusion if both evoked response and far-field signals are lacking (par. 0036) to avoid providing unneeded paces to the heart. Furthermore, it is well-known in the art to increase or decrease intervals to optimize pacing parameters to provide intervals that are customized for individual patients. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Florio's invention to patients with bundle branch block (par. 0007) to provide ventricular synchronization to patients lacking synchronization; detecting fusion if both evoked response and far-field signals are lacking (par. 0036) to avoid providing unneeded paces to the heart; and increasing or

decreasing intervals to optimize pacing parameters to provide intervals that are customized for individual patients.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Molin et al. (US 2001/0012953) is one of many references that teach of determining whether ventricular pacing pulses are delivered simultaneously and Struble (US 6,148,234) is one of many references that teach that the interventricular delay is less that 400ms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK
6/29/06

GEORGE R. EVANISKO
PRIMARY EXAMINER
6/29/6